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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,568	01/28/2004	James B. Grimes	JMG 3907.4	4044
321	7590	03/07/2006	EXAMINER	
SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			PELLEGRINO, BRIAN E	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SR

Office Action Summary

Application No.

10/766,568

Applicant(s)

GRIMES, JAMES B.

Examiner

Brian E. Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 10-13 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14-18 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/913,926.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/9/04, 2/22/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Specie F (for the prosthesis), Specie C (for the method of implanting) and Specie A (for the assembly to infuse agents) in the reply filed on 12/5/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly claims 10-13,19 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim.

Information Disclosure Statement

The information disclosure statement filed 4/9/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited *foreign patent document*; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The foreign patent GB 764600 was noted, but the information referred to therein has not been considered since the Examiner could not retrieve this reference. Is this a correct number? Send copy if possible.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: **715**. The drawings are also objected to as failing to comply with 37 CFR 1.84(p)(5) because they *do not include* the following reference sign(s) mentioned in the description: **739** mentioned in paragraphs 220,221,225,227. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Fahrer (DE 3704089). Fahrer discloses (Fig. 1) a bone prosthesis (1) comprising a stem with a tip and a collar (3) at the opposite end of the stem. It can be seen the prosthesis has a passageway (5) that extends from a first location to a second location. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. The prosthesis is fully capable of being implanted such that a portion of the stem is exposed to locations outside the bone. The passageway is fully capable of venting fluid from a first location to a second location and also wear debris. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. The prosthesis also has secondary channels (6) extending from the primary channel (5) to openings (4) in the bone prosthesis. The passageway also has an aperture (7) to sized and shaped to receive an infusion element. The infusion element (13) has threads (12) and the primary channel has threads (11) at the aperture adapted to engage the threads of the infusion element. It can be construed that there is an aperture (4) "generally" at the tip of the stem since they extend all the way down the

stem. With respect to claim 6, the one side of the prosthesis illustrates the channels in communication with a prosthesis-bone interface and at least the upper two secondary channels are at an oblique angle.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9,20-22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahrer (DE 3704089) in view of Grimes (WO 98/06359). Fahrer is explained supra. Fahrer also discloses the prosthesis having the channels enables a surgeon to deliver medicaments to the patient, see abstract. However, Fahrer fails to disclose a neck mounted on the collar on an end of the stem. Grimes teaches a femoral prosthesis (Fig. 6) having a collar 7 with a neck 5B' on an end of the stem opposite the tip. It would have been obvious to one of ordinary skill in the art to incorporate a collar with the neck on the collar as taught by Grimes using the prosthesis of Fahrer in order to provide more structural support for the device and better stability as it is worked on when introducing or removing fluids from Fahrer device. However, Fahrer does not disclose inserting the prosthesis in a way that the femur has been prepared with a seat on the femoral neck. With respect to the method of implanting, see Fig. 4B of Grimes to cut the neck of the femur, Fig. 4D drilling a passage through the shaft of the femur and Fig.

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4S shows insertion of the stem through the passage. Grimes also teaches the methods of preparing and milling the femur using the saw, drill, guide, etc. and inserting in the prepared passage, pages 20-36. Grimes additionally teaches this method of implanting preserves the trochanter and caps the femur to prevent microscopic debris from entering the interior bone, see abstract of Grimes. It would have been obvious to one of ordinary skill in the art to utilize the method of inserting a femoral prosthesis as taught by Grimes with the infusion type implant of Fahrer such that it enables the prosthesis to therapeutic treat the patient's bone while also preserving the upper portion of the bone.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-9,14-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5,7-10 of U.S. Patent No. 6740120. Although the conflicting claims are not identical, they are not patentably distinct from each other because this application's claims are merely broader than the patented claims of US 6740120. See *In re Goodman*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 7am to 4:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

